K122141

510(k) Summary

AUG 7 2012

Introduction

According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter

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Date prepared: August 03, 2012

Device Name

Proprietary name: IDS-iSYS IGF-I Calibration Verifier
Common name: IGF-I Calibration Verifier
Classification: 21CFR862.1660, Single (specific) analyte controls (assayed and unassayed),
Regulatory Class: Class I, reserved
Product Code: JJX

Predicate Device

The IDS-iSYS IGF-I Calibration Verifier is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys hGH CalCheck 5 (k103221)

Device Description

The IDS-iSYS IGF-I calibration verifer matrix is composed of a buffer solution containing bovine serum albumin with sodium azide as a preservative. The IGF-I peptide is added to this matrix and the resulting solution is lyophilised.

510(k) Summary continued

Intended Use

The IDS-iSYS IGF-I calibration verifier is a device intended for the verification of calibration of the IDS-iSYS IGF-I assay when performed on the IDS-iSYS multi-disciplined automated analyzer.

Comparison Table

Characteristic	IDS-iSYS IGF-I Calibration Verifiers (New Device)	Elecsys hGH CalCheck 5 (Predicate Device) k103221
Similarities		
Intended use/ Indications for use	Same	Used for assay calibration verification.
Format	Same	Lyophilized
Unopened Stability	Same	Store at 2-8°C until expiration date
Differences		
Analyte	IGF-I	hGH
Levels	4	5
Matrix	Buffered protein	Human serum matrix
Reconstituted Stability	On the analyzer: • up to 2.5 hours	On the analyzer: • up to 5 hours

Performance Characteristics

The ID-iSYS IGF-I Calibration Verifier was evaluated for value assignment and stability. See the following section for details.

Traceability

The IDS-iSYS IGF-I calibration verifier is traceable to the NIBSC code: 02/254 international standard.

Value Assignment

IDS-iSYS IGF-I Calibration Verifiers value assignment is performed as follows.

For each lot of the IDS-iSYS IS-3900 IGF-I assay kit available, a minimum of 15 assay runs is requested. Those runs must be performed using at least 3 independent iSYS machines. A minimum of 3 assay runs per iSYS machine is required.

Reagents, controls and samples are prepared according to the IDS-iSYS IGF-I Assay Instructions for Use IS-3900 and the IDS-iSYS IGF-I Control Set Instructions for Use IS-3930.

Each run consists of one iSYS calibration using the IDS-iSYS IGF-I IS-3900 Assay Reagent Cartridge, IDS-iSYS IGF-I IS-3900 Calibrators and the IDS-iSYS IS-3930 Control Set followed by samples (Calibration verifiers to test) and controls. Samples and controls are tested in triplicate.

For each Calibration Verifier, the final result reported is the mean value of all valid runs.

The customer acceptance range is calculated from the mean value based on 8% (standard deviation) for all Calibration Verifier.

Stability

IDS-iSYS IGF-I Calibration Verifiers stability testing was/is performed on the IDS-iSYS automated analyzer.

- Shelf-life stability

The accelerated stability testing supports an initial shelf-life claim of 6 months at 2-8°C. Real time testing at 2-8°C is on-going.

- Stability after reconstitution:

Real time testing was performed and supports the following claims: Reconstituted IDS-iSYS IGF-I calibration verifiers are stable for up to 2.5 hours on the board the IDS-iSYS. The IDS-iSYS IGF-I calibration verifiers are not stored on board the analyzer.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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AUG 7 2012

Re: k122141
Trade Name: IDS-iSYS IGF-I Calibration Verifier
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: July 16, 2012
Received: July 19, 2012

Dear Mr. Fenton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

K number **k122141**

Device **IDS-iSYS IGF-I Calibration Verifier**

The IDS-iSYS IGF-I Calibration Verifier is a device intended for verification of calibration of the IDS-iSYS IGF-I Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Prescription Use __X__ AND/OR Over-The-Counter Use __ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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